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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,137	08/29/2001	Christopher M. Angelucci	8932-538	6603

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EXAMINER

REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/942,137

Applicant(s)

ANGELUCCI ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08/22/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 13-21, 23-25, 27 and 53-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13-21, 23-25, 27 and 53-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 22, 2006 has been entered.

### ***Allowable Subject Matter***

The indicated allowability of claims 23-25, 27, 53-68 and 72-74 is withdrawn. Rejections based on the cited reference follow.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-6, 15-21, 23-25, 53, 54, 56, 58, 63-69 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapiro et al. (US Patent Number 6,436,139).

Art Unit: 3733

Shapiro et al. disclose various embodiments an implant comprising a body portion 10 having a length, a width and a depth (see figures 2-3). The body is insertable, i.e. capable of being inserted, between first and second cut bone segments. The body portion has an outer surface and an inner surface defining a substantially hollow region, 44, wherein the hollow region comprises most of the volume of the body portion. The body portion further has first and second longitudinal ends that communicate with the inner surface, wherein at least one of the first and second ends comprises a single bone receiving channel, e.g. 14 or 20, extending there across that has a first depth relative to a first side of the outer surface extending along the length of the body portion and a second depth relative to a second side opposite the first side, the first and second depths having different measurements, the first and second side regions having substantially the same contour (see figures 1-3 and 5A-5C). The body of the implant further comprises a longitudinal axis, e.g. 519, wherein the first and second bone engaging portions comprise concave cutouts, e.g. 514 and 520, wherein the cutouts further each comprise a centerline running parallel to the implant longitudinal axis and dividing each the cutouts, wherein the centerline of the cutout of the first end is offset from the implant longitudinal axis in one direction, and the centerline of the cutout of the second end is offset from the implant longitudinal axis in the opposite direction (see alternative embodiment of figure 12 and column 8, lines 19-22) The perimeter of the outer surface of the implant is a geometric circular/tubular shape (see figures 1-3 and 5A-5C). The channel includes at least two angled faces and they have an arcuate shape (see 1-3 and 5A-5C). The implant further includes at least

Art Unit: 3733

one hole or opening in communication with the outer surface and the inner surface (1-3 and 5A-5C). The implant is fabricate from biocompatible metal or another such material (see column 8, lines 37-40).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Shapiro et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 7-8, 13-14, 27, 55, 57, 59-62, 70-71 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al. (US Patent Number 6,436,139).

Shapiro et al. disclose the claimed invention except for the geometric shape being an ellipse. It would have been an obvious matter of design choice to one skilled in

Art Unit: 3733

the art at the time the invention was made to construct the implant of Shapiro et al. having a geometric shape like an ellipse, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of adapting the implant to the implant site. In re Dailey and Eilers, 149 USPQ 47 (1966).

With regard to claims 4, 57, 70 and 73, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. having a length ranging from about 11.5 to about 15.5 mm, a width ranging from about 8.0 to about 9.0 mm, and a depth ranging from about 5.5 to about 6.5 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 71 and 74, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. having a tubular wall thickness of about 1.0mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 7-8, 13-14, 27 and 59-62, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Shapiro et al. from bone allograft material or demineralized cortical bone, since it has been held to be within the general skill of a worker in the art to select a

Art Unit: 3733

known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-8 and 13-21 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendments to the claims resulted in a different interpretation of the Shapiro et al. reference, see rejections presented above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER